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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,398	02/10/2004	Donald K. Jones	CRD0869CONT1	8870
27777	7590	04/14/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,398

Applicant(s)

JONES ET AL.

Examiner

Jessica R Baxter

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07262004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 6,723,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because they each claim an embolization system having a catheter, a push rod and an embolization device with a foam sleeve.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cylindrical foam sleeve having a smaller normal expanded diameter than a diameter of the lumen of said catheter must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be

Art Unit: 3731

labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1- 9 and 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,238,403 to Greene, Jr. et al.

Greene discloses a vascular embolization system comprising a catheter (microcatheter 40), a push rod disposed in the lumen of the catheter (deployment instrument 30), an embolization device comprising an elongated coil or wire (carrier 14, Column 6 lines 37-57) the embolization device takes the shape of a helix (Column 8 lines 42-48), and a cylindrical foam sleeve disposed about said

Art Unit: 3731

coil (micropellet 12), said cylindrical sleeve has a hydrated normal expanded diameter and a smaller constrained diameter such that when unconstrained and hydrated said cylindrical foam sleeve returns to the normal expanded diameter (Column 5 lines 29-59), and said embolization device being disposed within the lumen at the distal section of said catheter, the distal end of the push rod engages the embolization device such that distal movement of the push rod causes the embolization device to exit the lumen of the catheter at a pre-selected position within the blood vessel (Column 7 lines 46-58). Greene discloses that the embolization device is comprised of a radiopaque material (Column 6 lines 14-25 and 37-46). Greene discloses that the embolization device is comprised of a therapeutic agent (Column 6 lines 26-36). Greene discloses that the cylindrical foam sleeve has a larger normal expanded diameter than a diameter of the lumen of said catheter (Column 5 line 55 – Column 6 line 7), that the cylindrical foam sleeve is a moldable foam material that is bonded to the coil (see Column 5 lines 24-54), that the coil comprises a lumen and said cylindrical foam sleeve is impregnated in said coil and extends into lumen of said coil (Column 5 lines 62-67 and Column 7 lines 1-4), that the cylindrical foam sleeve is a hydrogel (Column 5 lines 30-39), and that the embolization device includes a reinforcing material (Column 6 lines 7-13).

6. Claims 1, 2, 4, and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,165,193 to Greene, Jr. et al.

Greene discloses a catheter, a push rod, an embolization device comprising an elongated flexible cylindrical foam material (device 20); said embolization device being disposed within the lumen of the catheter (microcatheter 32), the distal end of the push rod (wire 22) engages the embolization device such that the distal movement of the push rod causes the embolization device to exit the lumen of the catheter (Column 7 line 33-Column 8 line 39). Greene discloses that the embolization device takes the shape of a helix or a convoluted shape (Column 8 lines 40-56), that

Art Unit: 3731

the foam material includes a radiopaque material (Column 7 lines 8-20), and that the foam material is a hydrogel (Column 3 lines 49-59).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greene, Jr. et al. '403 in view of U.S. Patent No. 4,890,612 to Kensey.

Greene discloses the claimed invention except for the reinforcing material is at least one fiber. Kensey teaches that fibers are used in a foam material to obtain a high expansion ratio and good mechanical wet strength (see Column 7 lines 34-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the foam material of Greene with the reinforcing fibers of Kensey in order to have a high expansion ratio and good mechanical wet strength.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3731



jrb



GLENN K. DAWSON
PRIMARY EXAMINER